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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,542	07/07/2003	Stephen M. Mullins	S0010-US02	8271
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GAMBRO, INC PATENT DEPARTMENT 10810 W COLLINS AVE LAKEWOOD, CO 80215			EXAMINER RIVELL, JOHN A	
			ART UNIT	PAPER NUMBER
			3753	

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,542

Applicant(s)

MULLINS ET AL.

Examiner

John Rivell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/4/05 (election).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 25-27 and 52-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 28-51 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 1-55 remain pending.

Applicant's election without traverse of the species of Group I, claims 1-24, 27-51 and 55, in the reply filed on October 4, 2005 is acknowledged.

Claims 25-27 and 52-54 are thus withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 4, 2005.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12, 14-16, 18-19, 22, 24, 32, 33, 36-38, 40-43, 47, 49, 51 and 55 are rejected under 35 U.S.C. §102 (b) as being anticipated by Fellows et al.

The patent to Fellows et al. discloses a "fluid flow control system for use with a fluid flow system for preventing a fluid that has reached a parametric limit from traveling to a point of use (at 1; "to process"); the fluid flow control system including two units; namely, a valve control unit (read on conductivity sensor AA1, controller AA2 and the electrical circuits operated thereby and connected thereto); and a hydraulic unit operably connected to the valve control unit; whereby the hydraulic unit has first (E) and second (A) valves and plumbing pieces to connect the first (E) and second (A) valves to each other and the fluid flow system; the first valve (E) being a two-way valve that is either closed in a no-flow position or is open to direct fluid from the fluid flow system to

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drain (sewer) when signaled to be at the appropriate state to open communication to a drain (sewer); and the second valve (A) is a two-way valve that is either open to flow through to the fluid flow system or may turn off flow to the fluid flow system when signaled to be at the appropriate state to close communication therewith” as recited in claim 1

Regarding claim 2, in Fellows et al., “the parametric limit is (read as) a preset alarm limit” as recited.

Regarding claim 3, in Fellows et al., “the first valve (E) is a solenoid valve” as recited.

Regarding claim 4, in Fellows et al., “the first valve (E) is (readable as) a normally closed valve” as recited. See for example column 4, lines 45-51 which disclose that either of the valves A, B, E, or F are “solenoid operated... through the agency of electric circuit opening or closing. Depending on whether one uses the disclosed circuit to open or close the valves upon energization of the circuit determines whether the valve is biased open or closed.

Regarding claim 5, in Fellows et al., “the first valve (E) is (readable as) a normally open valve” as recited. See the explanation above concerning claim 4.

Regarding claim 6, in Fellows et al., “the first valve (E) is a drain valve” as recited.

Regarding claim 7, in Fellows et al., “the second valve (A) is a solenoid valve” as recited.

Regarding claim 8, in Fellows et al., “the second valve (A) is (readable as) a normally open valve” as recited. See the explanation above concerning claim 4.

Regarding claim 9, in Fellows et al., “the second valve (A) is (readable as) a normally closed valve” as recited. See the explanation above concerning claim 4.

Regarding claim 10, in Fellows et al., “the second valve (A) is a to loop valve” a the term “to loop” is undefined in the specification and the art. The “second valve” disclosed in the application controls the flow of fluid to the process. The “second valve” A of Fellows et al. controls the flow of fluid to the process.

Regarding claim 12, in Fellows et al., “the system is used in non-dialysis fluid systems in which a sensor-initiated diversion of fluid flow (to sewer for example) is desired” as recited.

Regarding claim 14, in Fellows et al., “the system is used for preventing sub-standard quality water from reaching a point of use” as recited.

Regarding claim 15, in Fellows et al., “the system is configured for use with a water quality monitor” at conductivity sensor AA1 as recited.

Regarding claim 16, in Fellows et al., “the system is configured for use with a water quality monitor (AA1) which has an alarm power output, whereby the system uses the alarm power output issued by the water quality monitor for activation of the valve control unit” at valves E and A, as recited.

Regarding claim 18, in Fellows et al., “the system includes a fluid monitor (AA1) and the fluid monitor provides an AC signal for the alarm output” signal as recited.

Regarding claim 19, in Fellows et al., “the system includes a fluid monitor (AA1) and the valve control unit (AA2) is connected to a source of power and the fluid monitor (AA1) provides a signal for the valve control unit (AA2) to provide appropriate power to one or more of the first and second valves” A, E as recited.

Regarding claim 22, in Fellows et al., “the system includes a fluid quality monitor (AA1) and the fluid quality monitor provides an alarm signal to the valve control unit (AA2) that indicates that a fluid parameter has reached an alarm limit” as recited.

Regarding claim 24, in Fellows et al., “the system includes a fluid quality monitor (AA1) and the fluid quality monitor is a conductivity monitor which provides an alarm signal to the valve control unit (AA2) that indicates that fluid conductivity has reached an alarm limit” as recited.

Regarding claim 32, in making and/or using the device of Fellows et al. one necessarily perform a “method for diverting a fluid that has reached a preset alarm limit (e. g. a certain conductivity as sensed by conductivity sensor AA1) from reaching the point of use (at 1; “to process”); including: flowing a fluid through a fluid system which includes a flow control system for preventing a fluid that has reached a preset alarm limit from reaching the point of use (1); the fluid flow control system including two units; namely, a valve control unit (read at sensor AA1 and controller AA2); and a hydraulic unit operably connected to the valve control unit; whereby the hydraulic unit has first (E) and second (A) valves and plumbing pieces to connect the first (E) and second (A) valves to each other and the fluid system; the first valve (E) being a valve that directs water from the fluid flow system to drain (sewer) when signaled to be at the appropriate

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state; the second valve (A) is a valve that when signaled to be at the appropriate state turns off flow through the fluid flow system; and signaling the opening of the first valve (E); and the closing of the second valve (A) to divert the fluid from the point of use (1) to a drain (sewer)" as recited.

Regarding claim 33, in making and/or using the device of Fellows et al. one necessarily further performs the method step of "sensing when the fluid has reached a preset alarm limit" as recited.

Regarding claim 36, in making and/or using the device of Fellows et al. one necessarily further performs the method step "in which the valve control unit uses a water quality monitor" at AA1 as recited.

Regarding claim 37, in making and/or using the device of Fellows et al. one necessarily further performs the method step in which "the valve control unit uses a water quality monitor (AA1); whereby water quality is defined by a parameter selected from the group consisting of: resistivity, conductivity, pressure, temperature and flow". Here the sensor AA1 senses "conductivity" as recited.

Regarding claim 38, in making and/or using the device of Fellows et al. one necessarily further performs the method step "in which the valve control unit has a water quality monitor (AA1) which has an alarm power output and the alarm issues an alarm output which activates the valve control unit (AA2)" as recited.

Regarding claim 40, in making and/or using the device of Fellows et al. one necessarily further performs the method step in which "the first valve (E) is a normally closed solenoid valve which is connected to a drain" as recited.

Regarding claim 41, in making and/or using the device of Fellows et al. one necessarily further performs the method step in which “the second valve is a normally open solenoid valve which provides a connection to the fluid flow system” as recited. See the explanation concerning claim 4 above.

Regarding claim 42, in making and/or using the device of Fellows et al. one necessarily further performs the method step in which “the fluid monitor (AA1) provides an alarm signal to the Valve Control Unit (AA2) that indicates that fluid quality has reached the alarm limit” as recited.

Regarding claim 43, in making and/or using the device of Fellows et al. one necessarily further performs the method step in which “the Valve Control Unit (AA2) activates both of the first (E) and second (A) valves which opens the flow of the fluid to drain through the first valve (E), while closing the flow of fluid to the fluid system (1) through the second valve (A)” as recited.

Regarding claim 47, in making and/or using the device of Fellows et al. one necessarily further performs the method step in which “the fluid monitor (AA1) provides an AC signal for the alarm output” to the controller AA2 as recited.

Regarding claim 49, in making and/or using the device of Fellows et al. one necessarily further performs the method step in which “the system includes a fluid quality monitor (AA1) and the fluid quality monitor provides an alarm signal to the valve control unit (AA2) that indicates that a fluid parameter has reached an alarm limit and the valve control unit is connected to a source of AC power and thus provides AC power alarm output to power one or more of the first (E) and second (A) valves” as recited.

Regarding claim 51, in making and/or using the device of Fellows et al. one necessarily further performs the method step in which "the system includes a fluid quality monitor (AA1) and the fluid quality monitor is a conductivity monitor which provides an alarm signal to the valve control unit (AA2) that indicates that fluid conductivity has reached an alarm limit" as recited.

Regarding claim 55, in making and/or using the device of Fellows et al. one necessarily further performs the method step in which "the valve control unit (AA2) activates both of the first (E) and second (A) valves which opens the flow of the fluid to drain through one valve (E), while closing the flow of fluid to the main water circuit (1) through another valve (A)" as recited.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 28-31, 46, 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fellows et al.

Regarding claims 23 and 50, the patent to Fellows et al. discloses all the claimed features with the exception of having "resistivity" as the measured characteristic.

However, Official Notice is hereby made that it is widely known and notoriously old in the art that “conductivity” and “resistivity” are the inverse of each other and are considered to be full equivalents of each other within their inverse relationship.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ in Fellows et al. measurements of “resistivity” at sensors AA1, as opposed to conductivity for the purpose of sensing a desired characteristic of the fluid as recognized by the notoriously known inverse relationship of conductivity and resistivity.

Regarding claims 28-29, Fellows et al. discloses all the claimed features with the exception of having a “fail safe” mode of operation “restricting” or “continuing” the flow of fluid to the process upon “one of the first and second valves” failing.

However, this mode of operation depends on the particular failed valve being biased open or closed, depending on the type of operation, e.g. “continuing” or “restricting” fluid flow to the process. Given that in column 4, lines 45-51 Fellows et al. discloses that the valves A, B, E, and F may be biased open or closed, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ a particular arrangement of biased open and biased closed valves such that upon failure of a particular valve, the system “fails” in operation to restrict or preclude fluid flow to the process.

Regarding claims 30 and 46, Fellows et al. discloses all the claimed features with the exception of having a “solid state” relay at switches 100, 101, 102, 103.

However, Official Notice is hereby made that the utility of solid state circuit elements are notoriously old and well known in the art in terms of their long life and reliability over that of older, non solid state circuit elements.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ in Fellows et al. solid state circuitry elements at relays 100, 101, 102, 103 in place of the switch elements used in Fellows et al. for the purpose of switching on and of the valve elements as in Fellows et al. to take advantage of the known long life and reliability of well known and notoriously old solid state circuit elements.

Regarding claims 31 and 48, the comments above concerning solid state circuit elements apply as well. Additionally, it would have been obvious to one of ordinary skill in the art to employ DC current as opposed to the AC current, as used in Fellows et al. as it is well known and notoriously old in the art that AC and DC currents are full functional equivalents of each other.

Claims 11, 13 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fellows et al. in view of Yall et al.

The patent to Fellows et al. discloses all the claimed features with the exception of having utility in water treatment systems for dialysis, controlling the flow of de-ionized water.

The patent to Yall et al. discloses that it is known in the art to employ, in water purification systems, control of the flow of de-ionized water for dialysis purposes across the filtration system including bleeding water flow off to flow to drain, for the purpose of purifying water to be used in near aseptic purposes.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ the device of Fellows et al. in a water purification system controlling the flow of de-ionized water for the purpose of purifying water to near aseptic conditions for use in dialysis systems as recognized by Yall et al.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fellows et al. in view of Marcum.

The patent to Fellows et al. discloses all the claimed features with the exception of having "valve continuity testing of the circuitry" of the valve operator.

The patent to Marcum discloses that it is known in the art to employ a continuity testing feature within the electronic controller of the plurality of valves in an irrigation system for the purpose of automatically testing, and thus noting the test results in terms of operating or not operating, of the operability of the electric circuits operating the valves of the system.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ in Fellows et al. a circuit continuity testing arrangement in the electrical circuit for the purpose of automatically testing the operability of the circuit as recognized by Marcum.

Claims 17, 44 and 45 are 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fellows et al. in view of Austin et al.

The patent to Fellows et al. discloses all the claimed features with the exception of having "a remote alarm" capability.

The patent to Austin et al. discloses that it is known in the art to employ a remote alarm element at a central remote alarm station (column 8, lines 45-50) for the purpose of indicating to individuals at the remote location that an alarm condition is occurring.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ in Fellows et al. a remote alarm location for the purpose of permitting indication at that remote location the occurrence of an alarm condition as recognized by Austin et al. Regarding claim 45, note in particular that Austin et al. also discloses utility in combination with a dialysis machine.

Claims 20 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fellows et al. in view of Newton.

The patent to Fellows et al. discloses all the claimed features with the exception of having "LEDS" indicative of an particular condition.

The patent to Newton discloses that it is known in the art to employ "LEDS" at invertible LED light 78 for the purpose of indicating, by color, a certain alert condition.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ in Fellows et al. a LED light for the purpose of indicating a certain alert condition as recognized by Newton.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Rivell whose telephone number is (571) 272-4918. The examiner can normally be reached on Mon.-Thur. from 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Blau can be reached on (571) 272-4406. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Rivell
Primary Examiner
Art Unit 3753

j.r.